IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent Application No. 10/089,009

Applicant: Goldman et al.

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Examiner: Dong Jiang

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DECLARATION UNDER 37 C.F.R. § 1.132 OF THOMAS WALDMANN, M.D.

I, Thomas A. Waldmann, hereby declare that:

1. I am the Chief of the Metabolism Branch of the Center for Cancer Research at the National Cancer Institute (NCI), and a co-inventor of the subject patent application.

2. I have reviewed Colamonici et al., *J. Immunology*, *145*, 155-160 (1990) ("the Colamonici reference"), and understand that the Colamonici reference has been cited in the Office Action dated April 19, 2005, as allegedly anticipating the subject matter of the pending claims.

3. Using cross-linking and immunoprecipitation studies, the Colamonici reference discloses the identification of two polypeptides having a molecular weight of 37 kDa and 20 kDa, each of which reportedly associates with the p95-110 subunit of the IL-2 receptor (IL-2R) (see Colamonici reference at, e.g., page 159, second column).

4. The Colamonici reference further discloses the use of monoclonal antibodies anti-Tac and 7G7/B6 to immunoprecipitate IL-2R alpha and polypeptides associated

therewith, including the 37 kDa and 20 kDa polypeptides described above (see Colamonici reference at, e.g., page 159, second column).

5. The anti-Tac and 7G7/B6 monoclonal antibodies each recognize and bind to different epitopes of the alpha chain of IL-2R, which is also known in the art as CD25.

6. Work from my laboratory demonstrates that when lysates from cells which bind the monoclonal antibody anti-Tac are first pre-cleared with anti-Tac to remove all components which may bind to the anti-Tac antibody, and then are directly immunoprecipitated with the 5F7 antibody (i.e., the monoclonal antibody produced by the hybridoma PTA-82), the interleukin-2 receptor associated polypeptides (ILRAP) of 32-34 kDa and 26-28 kDa described in the subject application are still present. As such, these data demonstrate that the 32-34 kDa and 26-28 kDa ILRAPs are not recognized by the anti-Tac monoclonal antibody in the pre-clearing step.

7. Furthermore, the presence of ILRAPs described in the subject application can be demonstrated in a particular cell line where CD25 is not expressed and, therefore, these polypeptides cannot be recognized by the anti-Tac and 7G7/B6 monoclonal antibodies, but are recognized by the 5F7 monoclonal antibody. This work further indicates that the polypeptides described in the Colamonici reference are not capable of forming a complex with the monoclonal antibody 5F7 (i.e., the monoclonal antibody produced by the hybridoma PTA-82).

8. I hereby declare that all statements made herein of my own knowledge are true, that all statements made on information and belief are believed to be true, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: June 17 2005

Thomas A. Waldmann, M.D.